IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***Case listed on attached Exhibit 1***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MOTION TO EXCLUDE CERTAIN OPINIONS OF RICHARD BERCIK, M.D. AND SUPPORTING MEMORANDUM

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this brief in support of their motion to limit the general and case-specific opinions of Plaintiffs' expert, Richard Bercik, M.D., in this case. Specifically, the Court should preclude Dr. Bercik from providing general causation opinions on corporate knowledge and that exceed his expertise. His specific causation opinions that exceed his qualifications should also be precluded, as should his opinions that lack a reliable foundation or that are speculative. *See* Ex. A, Richard Bercik, M.D. (Aug. 2019) Freeman Report ("Report").

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.,* 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should exclude Dr. Bercik's general opinions about Defendants' supposed knowledge or state of mind.

In his Report, Dr. Bercik claims to have knowledge about various risks and about information supposedly available to Defendants. These assertions are based on mere speculation. Examples set forth in Dr. Bercik's expert report include:

- "Ethicon *was aware* of the complications associated with the support arms at least 14 months prior to Terri Freeman's Prolift+M implant procedures." Ex. A, Report at 17 (emphasis added).
- "Contraction of polypropylene surgical mesh in the body has been described in multiple peer-reviewed publications. This phenomenon results in long-term complications, including erosion, loss of elasticity, mesh contraction, nerve damage, and vaginal scarring. Ethicon *was aware* of this problem as early as January of 2005." *Id*. at 20 (emphasis added).

As a threshold matter, any second-hand testimony about Ethicon's knowledge, motives or intentions must be excluded. An expert qualified as a physician "is not qualified by 'knowledge, skill, experience, training or education' to opine on Ethicon's state of mind or knowledge." *Lewis v. Ethicon*, No. 12-cv-4301, 2014 WL 186872, *15 (S.D. W. Va. Jan 15, 2014). The court also found that "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Id*. at *6. That rule applies here: Dr. Bercik does not have any specialized knowledge that would enable him to testify about what Ethicon employees knew or believed, so his opinions about Ethicon's knowledge are not helpful to the factfinders in this case. There is nothing about Dr. Bercik's training and experience as a pelvic surgeon that affords him special expertise or clairvoyance that would somehow enable him to testify about the Defendants' knowledge.

Nor does the jury need Dr. Bercik's help reading documents. There is nothing about Dr. Bercik's background as a medical doctor that will help the jury better understand what employees of a corporation wrote or said. Expert testimony is only appropriate for matters

beyond the knowledge of the average layperson. Fed. R. Evid. 702(a); *Hines v. Wyeth,* No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness"). To the extent that Dr. Bercik's opinions are based on his review of documents that Plaintiff's counsel selectively presented to him, they concern lay matters which a jury is capable of understanding without the expert's help. *See In re: Trasylol*, 709 F. Supp. 2d 1323, 1346-47 (S.D. Fla. 2010) (excluding expert's testimony, including expert's references to defendant's internal documents, finding that the expert was simply "Plaintiffs' advocate rather than expert").

For these reasons, this Court should preclude Dr. Bercik from testifying about Ethicon's knowledge gleaned from his review of corporate documents or otherwise.

II. The Court should preclude Dr. Bercik from rendering an opinion on biomaterial properties of mesh or mesh design because he is not qualified to do so.

Dr. Bercik is not qualified by education, training or experience to opine on biomaterials science issues, including, without limitation, polypropylene mesh tissue reactions, mesh contraction, stiffness, porosity, bridging fibrosis or tissue in-growth. He does not have an engineering degree in materials science, nor has he attended classes in materials science when in training. *See* Ex. B, Bercik Curriculum Vitae. He does not have a demonstrated background in polymer chemistry or biochemical or biomechanical engineering, and his disclosed background indicates that he has never performed any bench research with respect to polypropylene. *See id.* He has done no research on the properties of polypropylene and has not published any papers on it. *Id*. His testimony is not only anecdotal; it also has no scientific verification.

In other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and limited to experts

with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.D. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). In the present case, Dr. Bercik's lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh.

Additionally, Dr. Bercik has no medical device design expertise that would otherwise qualify him to opine regarding the design of these medical devices. *See* Ex. A, Bercik Report at 20 ("The design of the Prolift [sic] resulted in severe scarring resulting in tissue contraction and distortion."). There is no evidence that he has designed a mesh-based device, and he has not published any articles about device design. *See, e.g.*, *Tyree v. Bos. Sci. Corp.*, No. 2:12–cv–08633, 2014 WL 5486694, at *47 (S.D. W. Va. Oct. 29, 2014) (Dr. Blaivas not qualified to opine on product design; his experience removing SUI devices and observing complications during removal did not, alone, render him qualified to opine as to design; nor did his work in developing a different sling qualify him as an expert in the design of a medical device). Dr. Bercik does not have the qualifications to offer design opinions. Accordingly, Dr. Bercik's opinions regarding design defect are mere speculation and should be excluded.

III. Dr. Bercik is not qualified to offer any opinions on product warnings.

Dr. Bercik does not specify any intention to testify regarding the product warnings until this statement in his conclusion: "In addition, Ethicon failed to adequately warn of the risks of this device and procedure, further exacerbating the unreasonably dangerous nature of the device and procedure." Ex. A, Report at 24. He did not offer this opinion or any support for it in the body of his Report. He did not offer any warning opinion in his deposition. This makes sense given that Dr. Bercik is not qualified to opine on the adequacy of the Prolift+M or TVT-O product warnings. Indeed, Dr. Bercik's report sets forth none of the qualifications that this Court has looked for in order for an expert to offer any opinion about product warnings. *See, e.g.*, *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (excluding expert's warnings opinions because he "is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings" and because an "expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.").

Further, any such opinion improperly includes legal terminology, which this Court has also disallowed. *Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *10 (S.D.W. Va. Feb. 27, 2015) (excluding expert's opinions that product manufacturer "failed to provide warnings or instructions to adequately inform users of the dangers associated with using the device" as improper legal conclusions). As a result, Dr. Bercik should be precluded from offering any opinion concerning the Prolift+M or TVT-O warnings.

IV. The Court Should Exclude Certain of Dr. Bercik's Case-Specific Opinions.

A. Dr. Bercik's case-specific opinions that are tied to his improper opinions concerning biomaterials and design should be excluded.

Most of Dr. Bercik's causation opinions are premised upon his general opinions about the material characteristics of Prolift+M and TVT-O—opinions that he is not qualified to give and that are not based on any testing of the Prolift+M or TVT-O by him. Specifically, according to Dr. Bercik's report and without citation to any source, Prolift+M has a "relatively high stiffness [and] low effective porosity." Ex. A, Report at 19. Dr. Bercik then claims that this creates "negative tissue reactions," "increased chronic tissue inflammation," "effects on the surrounding tissue" and "significant tissue reaction with chronic inflammation" allegedly resulting in Ms. Freeman's dyspareunia, vaginal pain, vaginal contraction, anatomic distortion of the vagina, pelvic floor disorder, abdominal pain, urinary retention, voiding dysfunction, urge incontinence, and lower urinary tract symptoms.[1] *Id*. at 18-23.

Dr. Bercik is a urogynecologist. He is not a materials scientist. He has no specific specialized training or knowledge of the material characteristics of polypropylene mesh. *See* Ex. B, Bercik CV. He has not written any articles or authored any reports on the material characteristics of polypropylene mesh nor has he engaged in research to study those material characteristics. There is nothing in Dr. Bercik's background, experience, training, or education that qualifies him to opine that Prolift+M is excessively stiff or has a low effective porosity, much less for him to then detail the effect of any such properties on surrounding tissue. The same is true for his assertion that the TVT-O mesh caused tissue fibrosis or contracted. Ex. A, Report at 22.

Nor is Dr. Bercik qualified to opine that both mesh products degraded, and his opinion in this regard wholly lacks a scientific basis. He has not performed any tests or personally analyzed Ms. Freeman's excised mesh. His Report cites to no study, testing, medical literature or any

[1] Dr. Bercik expressly denied that he connects Ms. Freeman's claimed recurrent urinary tract infections to either mesh product. Ex. C, Bercik Dep. at 80:19-23.

other source as the basis for his statements. He admits that the only pathology reports he reviewed did not include any opinion about mesh degradation. Ex. C, Bercik Dep. at 72:3-9 ("So degradation is not something that pathologists typically look for. The hospital pathologist is not looking for a degradation of the mesh. So no pathology report from any hospital that has been -- that -- to my knowledge, has done the examination required to find degradation in material."). Therefore, Dr. Bercik's predicate opinion about mesh characteristics is only an unqualified and speculative assertion that Dr. Bercik relies upon to support his argument that Prolift+M and TVT-O cause tissue changes or inflammation.

More is needed than ipse dixit to render an expert's opinion admissible. Courts routinely exclude opinions under *Daubert* where the experts inappropriately extrapolate far beyond the data as Dr. Bercik does here. *See*, *e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that neither "*Daubert* [n]or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"). Dr. Bercik's opinions regarding dyspareunia, contraction and distortion of the vagina because of the mesh have no basis other than his ipse dixit.

B. Dr. Bercik lacks both the qualifications and a proper foundation to opine that Prolift+M or TVT-O characteristics resulted in tissue reaction or inflammation in Ms. Freeman's body.

In addition to being unqualified as a material sciences expert, Dr. Bercik is also not a pathologist, polymer scientist or biomaterials specialist. The fact that Dr. Bercik possesses none of these specialties, however, has not stopped him from opining that the alleged characteristics of mesh cause "negative tissue reactions such as bridging fibrosis and poor tissue in-growth" as well as inflammation that causes excess scar fibrosis in Ms. Freeman's body. Ex. A, Report at 19. Such opinions are the realm of pathologists, but Dr. Bercik has not been trained in pathology, has not performed any tests, and cites to no specialized knowledge or publications on

the topic. And as previously noted, he expressly disclaimed any reliance on pathology reports in this case. Ex. C, Bercik Dep. at 72:3–73:24. His opinions, therefore, are baseless, unreliable and inadmissible.

C. The basis for Dr. Bercik's opinions concerning mesh degradation does not meet Daubert standards.

Dr. Bercik opines that degradation is a "substantial factor in causing the scarring and resulting shrinkage and injuries;" that degradation caused "surface changes;" and that degradation causes increased inflammatory response and tissue damage. Ex. A, Report at 19, 20, 22. Dr. Bercik lacks an adequate basis to say that Ms. Freeman's mesh degraded at all. He admitted in his deposition that he has no proof that Ms. Freeman's mesh degraded:

> Q. Did you see any evidence in the pathology reports or any other records of mesh degradation of Ms. Freeman's mesh?
>
> A. So degradation is not something that pathologists typically look for. The hospital pathologist is not looking for a degradation of the mesh. So no pathology report from any hospital that has been -- that -- to my knowledge, has done the examination required to find degradation in material.

Ex. C, Bercik Dep. at 72:6-13. Because he lacks a scientifically sustainable basis for his opinion on degradation of Ms. Freeman's mesh, Dr. Bercik turns to statistics:

> Q. So do you know, one way or another, Doctor, if the Prolift+M mesh or the TVT-O mesh that was implanted in Ms. Freeman degraded?
>
> A. Well, I know -- I know that the preponderance of the evidence is that more than 50 percent of them -- so to a medical probability, it has. That's what I know.
>
> Q. . . . But you cannot say with certainty that the specific mesh that was implanted in Ms. Freeman degraded. Is that fair?
>
> A. Well, when you use the word "certainty," I can't probably say that about very much of anything. So, you know, you're right. That mesh has not been looked at.

> But when we talk about whether or not, you know, more than -- the -- the majority of them have degraded, the majority of them will have degraded. I can't say for sure in hers, 'cause I don't believe it's been looked at.

Id. at 72:3–73:24. Given that the only basis for his opinion that Ms. Freeman's mesh degraded and caused injury is based on roughly 50/50 odds, this opinion lacks a reliable scientific basis and should be excluded.[2] And he specifically disclaimed any reliance on the pathology reports regarding Ms. Freeman's explanted mesh in forming his opinions here. *See* Ex. C, Bercik (10/1/19) Dep. at 72:3–73:24 (cannot say that Plaintiff's mesh degraded because the "mesh has not been looked at.").

D. The Court should preclude testimony about Ms. Freeman's speculative future injuries.

The Court should also preclude Dr. Bercik from testifying that Ms. Freeman will require future treatment "as a result of the scarring and nerve damage/entrapment caused by the Prolift+M and TVT-O devices." Ex. A, Report at 23. As noted above, Dr. Bercik has no support for his opinion that Ms. Freeman has any such tissue changes or inflammation. Such testimony amounts to inadmissible speculation. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 619 (S.D.W. Va. 2013) ("An expert's opinions must be based on reliable principles and methods applied to the facts of the case.").

Whether the residual mesh in Ms. Freeman places her at risk to suffer from new or worsened complications in the future is not relevant to the underlying product liability dispute.

[2] Plaintiff's case-specific pathologist, Dr. Paul Michaels, produced a report dated August 7, 2019. Contrary to Dr. Bercik's testimony from October 1, 2019, her explanted mesh had in fact "been looked at." Ex. C, Bercik Dep. at 73:18-19. Dr. Bercik's report was completed on August 15 or 16, 2019. Ex. C, Bercik Dep. at 9:3-4. His deposition was taken October 1, 2019. Thus, Dr. Bercik had the opportunity to review and rely upon the pathology report both before his report was produced and before his deposition. He did not, and he cannot attempt to backfill his unreliable opinion now. *See Claar v. Burlington N. R.R.*, 29 F.3d 499, 502-03 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method.").

That a defendant's conduct merely exposes a plaintiff to a risk of injury is an insufficient basis for recovery. An injury must arise from that risk and the plaintiff must have been harmed. Dr. Bercik's opinions do not identify a cognizable or recoverable injury. Accordingly, his opinions regarding future injury lack an adequate foundation, do nothing to assist the jury and are inadmissible under Fed. R. Evid. 702. *See*, *e.g.*, *Williams v. Int'l Paper Co.*, No. 108-045, 2009 WL 10678735, at *5 (S.D. Ga. June 30, 2009) (though expert could testify "to a reasonable degree of medical certainty" that Cushing syndrome is a known consequence of taking corticosteroids, he could not testify that the plaintiff may, or will, develop Cushing syndrome as a result of his exposure)

E. Dr. Bercik's reference to erosion is not supported here.

Dr. Bercik says that "Tissue reaction to the mesh and mesh erosions caused excess scarring in the tissues…" Ex. A, Report at 20. Yet Dr. Bercik testified that Ms. Freeman never had a mesh erosion or exposure. Ex. C, Bercik Dep. at 65:20–66:5. Expert testimony that is not based on the record "offers no assistance to the trier of fact in understanding the evidence because it lacks an adequate foundation in the evidence of the case." *Harrison v. United States*, No. 2:07-00696, 2009 WL 36545, at *7 (S.D.W. Va. Jan. 6, 2009). Any opinion concerning mesh erosion as a cause of excess scarring should be excluded.

CONCLUSION

For these reasons, the Court should limit Dr. Bercik's opinions consistently with the foregoing.

Respectfully submitted,

/s/ *William M. Gage*
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010

(601) 985-4561
william.gage@butlersnow.com

/s/ *Susan M. Robinson*
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

Counsel for Defendants Ethicon, Inc. and Johnson & Johnson

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage